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NEWS

Montana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Allowable Changes to Schedule II Prescriptions

The Montana Board of Pharmacy receives occasional questions regarding what, if any, changes can be made to Schedule II prescriptions without requiring a new prescription from the practitioner. **After consulting with the prescribing practitioner**, the pharmacist may add the dosage form to the prescription or change the patient's address, drug strength, drug quantity, and directions for use. The pharmacist may add information provided by the patient or patient's agent such as the patient's address. **The pharmacist is never permitted to make changes to the patient's name, name of the controlled substance prescribed (with the exception of generic substitution), or the signature of the prescribing practitioner.** This allows for the majority of corrections to be dealt with via a phone call. The pharmacist should always document the time and date that the prescriber was contacted and should always ask the prescriber to document the change in the patient's chart so that both parties have a record of the conversation.

Our Neighbors to the North: Importation of Canadian Prescription Drugs

Food and Drug Administration (FDA) has stated that "virtually all Canadian pharmacies that ship prescription drugs to consumers in the US violate US law because such drugs are generally unapproved (21 USC 355), labeled incorrectly (21 USC 353(b)(2) and/or dispensed without a valid prescription (21 USC 353 (b)(1))." FDA may refuse admission to any drug that "appears" to be unapproved, placing the burden on the importer to prove that the drug is, in fact, FDA approved. Unfortunately, at this time FDA seems woefully unprepared to enforce all but the most blatant cases of drug reimportation.

FDA is also "concerned about legislative initiatives that, while intended to provide drug price relief to consumers, would severely damage the system of drug regulation that has come to be known as the 'gold standard' for drug safety throughout the world." US Department of Health and Human Services Secretary Tommy G. Thompson, speaking at a biotechnology summit in Canada this past summer, said, "Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired and contaminated drugs and drugs stored under inappropriate and unsafe conditions."

A recent FDA letter to our Board stated that importation for personal use (generally a three-month supply or less)

"may be allowed at the discretion of FDA personnel in situations where there is an approved treatment in the US, but for medical reasons the treatment is unacceptable or cannot be tolerated by the patient and a foreign version of the treatment is available that may be acceptable." In addition, a person who has received treatment in a foreign country is allowed to continue that treatment after his or her return to the United States. The policy is **not** intended to allow importation of less expensive foreign versions of drugs that are approved in the US. Prescription drug reimportation for purposes of commercial distribution, such as recent newspaper advertisements from US mail-order and Internet pharmacies promoting reimported Canadian drugs, is also a clear violation of federal law. The National Association of Boards of Pharmacy® recently sent a clearly worded letter to Secretary Thompson and Dr Mark McClellan of FDA urging them to enforce their own laws with regard to drug reimportation.

Importation of prescription drugs from Canada does not seem to raise the same concerns that drug reimportation from Mexico or India does. However, Canada has started to experience drug shortages due to the unprecedented drain of prescription drugs into this country. This will become an even greater factor as more US consumers turn to Canada for relief from high drug prices, and drug companies continue to examine ways to restrict the flow of drugs into Canada destined to take a "revolving door" route back into the US. There is speculation that Canadian drug exporters will turn to countries such as Mexico and India to maintain their supply and present windfall of profits. Many of the countries that Canada is likely to purchase from are thought to have a relatively high incidence of counterfeit drug distribution. The chances of harm to American patients are bound to increase as a result.

Our Board has recently sent a position paper to all Montana pharmacies and major newspapers in an effort to educate the public on the legality and potential risks of drug reimportation. The National Association of Chain Drug Stores, Inc, has lead other groups in mounting an educational campaign on this subject as well. Washington must work to ensure that patients in this country have access to affordable medications without having to risk problems inherent in obtaining medications from a foreign source.

Patient Counseling: How Do You Measure Up?

The Schering Report, a study conducted annually by an independent research firm for Schering Laboratories, examines trends affecting the profession of pharmacy. The 2002 report contains both encouraging and alarming statistics:

- ◆ Only 81% of patients are always told by the prescribing practitioner what the drug is for. If not told, they would rarely ask.
- ◆ Only 67% of patients are always told by the prescribing practitioner how to take a new drug, and 44% are rarely or never told about adverse reactions.
- ◆ Forty-nine percent are never given written information about a new drug by their physician or staff. They rarely if ever ask for written information if it has not been offered.

Given the above statistics, patient counseling by the pharmacist takes on even greater importance. Over 75% of chain pharmacies and 66% of independent pharmacies have a dedicated patient counseling area, ranging in scope from separate rooms with video capabilities to short walls restricting the view of the counseling window from other areas in the pharmacy; and, hopefully, blocking counseling conversations as well.

On July 1, 2003, all Montana pharmacies will be required to have a counseling area that provides **visual and auditory privacy**. Please contact Becky at the Board office at 406/841-2355 if you have questions.

Technician Tidbits

The Board's compliance officer continues to encounter unlicensed technicians performing their duties despite the fact that technician licensure has been required for nearly 18 months. The honeymoon is over. Unlicensed technicians found to be performing the duties of a technician will be told to cease and desist. Disciplinary actions will follow.

A reminder: 24.174.705 (g) requires a technician answering the phone to **"identify themselves as a technician."** This is a simple matter designed to protect both the patient and technician. It needs to be done consistently.

Pharmacy Recovery Network Notes

The Montana Pharmacist Recovery Network is being established to help Montana pharmacists, interns, students, and technicians whose health or performance has been adversely affected by chemical dependency. A pharmacist will answer

self-referrals as well as those of coworkers or family on a 24-hour basis. **All calls will remain confidential.**
Phone: 406/327-1250.

Institute for Safe Medication Practices

We are all concerned about patient safety. To reduce the risk of errors, effective reporting mechanisms are essential to learn about the breakdowns leading to medication errors. The Institute for Safe Medication Practices' Web site, www.ismp.org, provides important alerts regarding the prevention of medication errors. From look-alike and sound-alike drugs, to cautions on different strengths (Infant's Tylenol Concentrated Drops (acetaminophen 100 mg/ml) versus children's acetaminophen elixir (at 160mg/5ml), to the recurring confusion between tincture of opium and paregoric, to the possible hazard of asphyxiation of syringe caps when syringes are used to measure and administer medications for children, to updates in bar coding, this is a very useful Web site.

Update: Board of Pharmacy Meetings Scheduled for 2003

April 8-9.....301 S Park, Helena
July 15-16.....301 S Park, Helena

The fall meeting has been moved to **October 30-31, 2003**, at the Sheraton in Billings, MT, to coincide with the Montana Pharmacy Association meeting October 31 and November 1-2. If you would be interested in having the Board meet in your area in 2004, please contact the Board office at 406/841-2356.

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